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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

MARK L. SHURTLEFF, ATTORNEY GENERAL OF THE STATE OF UTAH, *ex rel.* THE STATE OF UTAH,

Plaintiff,

v.

JANSSEN ORTHO LLC, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., and ASTRAZENECA PHARMACEUTICALS LP,

Defendants.

Case No. 2:10-CV-00519-BSJ

DEFENDANTS' JOINT MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION

[ORAL ARGUMENT REQUESTED]

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STATEMENT OF ISSUES

1. Does one or more of the State of Utah's claims raise substantial and disputed federal questions about the State's obligation under the Federal Medicaid statute to reimburse for prescriptions for Utah Medicaid participants, and about the interpretation and application of the term "medically accepted," as used in the Federal Medicaid statute?

Suggested Answer: Yes.

2. May this Court exercise federal jurisdiction over this case without disturbing the balance of federal and state judicial responsibilities?

Suggested Answer: Yes.

INTRODUCTION

The State of Utah ("State" or "plaintiff") brings claims against defendants Janssen Ortho LLC and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively, "Janssen") and AstraZeneca Pharmaceuticals LP ("AstraZeneca") based on allegations that defendants "illegally" promoted the off-label use of Risperdal® and Seroquel® and made "false representations" about these medicines that induced the State to allow the distribution of Risperdal and Seroquel to Utah Medicaid participants. The State's claims raise substantial and disputed federal issues, as resolving them will require the Court to answer questions about (1) the State's obligation, under the Federal Medicaid statute, to reimburse for prescriptions of Risperdal and Seroquel; and (2) the interpretation and application of the term "medically accepted," as used and defined by the Federal Medicaid statute, 42 U.S.C. § 1396r-8(d), (k)(6).

The State attempts to avoid federal question jurisdiction by crafting only state-law claims in its Amended Complaint. However, the United States Supreme Court has rejected such attempts to avoid federal jurisdiction and has recognized that federal question jurisdiction is appropriate where, as here, the allegations raise substantial and disputed federal issues that can be adjudicated without disturbing the balance of federal and state judicial responsibilities.

In it motion to remand, the State ignores the "contextual enquiry" mandated by the United States Supreme Court. However, the allegation-specific, case-by-case analysis required by Supreme Court precedent establishes that the exercise of federal jurisdiction over this case is appropriate. Accordingly, the State's motion to remand should be denied.

STATEMENT OF FACTS

1. In this case, the State makes claims against defendants concerning Risperdal and Seroquel, two prescription medicines approved by the U.S. Food and Drug Administration ("FDA").

2. Risperdal and Seroquel belong to a class of medicines known as "atypical" or "second generation" antipsychotics.

3. Risperdal is sold by Janssen; Seroquel is sold by AstraZeneca.

4. The State is a voluntary participant in the Federal Medicaid program.

5. Under the Federal Medicaid program, states may elect to provide benefits such as coverage for prescription drugs to eligible individuals. *See* 42 U.S.C. § 1396(i)(10)(A).

6. At all relevant times, the State elected to provide prescription drug benefits to Medicaid participants.

7. Once the State elected to provide a prescription drug benefit under the Federal Medicaid statute, it was obligated to comply with certain requirements set forth in that federal law. *Id.* § 1396r-8.

8. Under these requirements, the State must reimburse for a "covered outpatient drug," with very limited exceptions and few permissible restrictions, none of which is implicated by the State here. *Id.* § 1396r-8(d).

9. The Federal Medicaid statute defines a "covered outpatient drug" as a drug, subject to a Medicaid Rebate Agreement, that "is approved for safety and effectiveness as a prescription drug" by the FDA and is prescribed for outpatient use, subject to some exceptions, for a "medically accepted indication." *Id.* § 1396r-8(k)(2), (k)(3).

10. There is no dispute that both Risperdal and Seroquel have, at all relevant times, been "covered outpatient drugs."

11. The term "medically accepted" is defined in the Federal Medicaid statute; it encompasses both FDA-approved or "on-label" uses of a covered outpatient drug *and* any non-FDA-approved or "off-label" uses "supported by one or more citations included or approved for inclusion in any of the compendia described in" the statute. *Id.* § 1396r-8(g)(1)(B)(i), (k)(6).

12. In Count I, however, the State takes the position that all off-label prescriptions of Risperdal and Seroquel are for non-medically accepted indications and, therefore, it need not reimburse for any off-label prescriptions of Risperdal or Seroquel. (Am. Compl. ¶¶ 125-28.)

13. In Count IV of its Amended Complaint, the State seeks reimbursement of the cost of every Risperdal and Seroquel prescription ever written for a Utah Medicaid participant – whether on-label, off-label, supported by the compendia, or not supported by the compendia – based on allegations that Janssen and AstraZeneca made "false representations" to the FDA, the State, and others, and that these representations supposedly "induc[ed] the State to allow the distribution of Risperdal and Seroquel to participants in the Utah Medicaid Program." (*Id.* ¶¶ 148, 151-52.)

ARGUMENT

I. SUMMARY.

In an improper attempt to recast its reimbursement rights and obligations under the Federal Medicaid statute, the State here raises claims that hinge on (1) whether the Federal Medicaid statute authorizes the State to refuse to pay for – or requires the State to pay for – prescriptions for defendants' atypical antipsychotics, and (2) the interpretation and application of the term "medically accepted" as used in the Federal Medicaid statute. Thus, this case "belongs in a federal court" because the State's claims "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005).

There is a powerful national interest in providing a federal forum for this action because the case involves the interpretation of key provisions of an important federal statute – the Federal Medicaid statute – that implicate the statutory rights and obligations of every state in the Union. The Court may exercise federal jurisdiction over this action, and decide the federal issues it presents, without upsetting the congressionally approved balance of federal and state judicial responsibilities.

II. FEDERAL JURISDICTION EXISTS UNDER *GRABLE*.

The United States Supreme Court has recognized "for nearly 100 years that in certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues." *Grable*, 545 U.S. at 312. This "doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on

substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.*

Pursuant to *Grable*, there is federal subject matter jurisdiction over this case because the resolution of claims raised by the State turns on a determination of the nature and extent of the State's rights and obligations under the Federal Medicaid statute to reimburse – or to refuse to reimburse – for prescriptions for FDA-approved medicines. The determination of this issue for at least some of the State's claims necessarily rests on the interpretation and application of the federal statutory term "medically accepted."

A. Federal Jurisdiction Exists Over the State's Claims Because They Raise Disputed and Substantial Federal Issues.

A defendant has a right to remove any case of which the district court would have had original jurisdiction. *See* 28 U.S.C. § 1441(a). District courts have "original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." *Id.* § 1331. Under *Grable*, "arising under" jurisdiction exists not only over federal-law claims, but also over state-law claims which "necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314.

In *Grable*, the Court considered whether there was federal jurisdiction over a state-law quiet title action brought by a landowner against the tax sale purchaser of his property. The Internal Revenue Service had seized the landowner's property to satisfy his federal tax delinquencies and then sold the property. *Id.* at 311. Although the landowner received notice of the seizure and the sale, he brought a state-law quiet title action, alleging that the Internal Revenue Service had not notified him of the seizure in the manner required under the relevant

federal statute. *Id.* The Court recognized that the landlord's state-law claim turned on whether he received adequate notice, as defined by federal law, and held that this question was properly answered in federal court. *Id.* at 314, 319-20.

Since the decision in *Grable*, numerous courts have concluded that federal jurisdiction exists over state-law claims in circumstances analogous to those presented here. For example, in *Nicodemus v. Union Pacific Corp.*, 440 F.3d 1227 (10th Cir. 2006), the Tenth Circuit held that there was federal question jurisdiction over the plaintiffs' state-law claims. In *Nicodemus*, Union Pacific had given certain telecommunications companies the right to install and maintain fiber-optic cables in its railroad rights of way. *Id.* at 1233. Plaintiffs alleged that Union Pacific had given away rights it did not possess under the federal right-of-way statute and brought state-law claims for, *inter alia*, trespass and unjust enrichment. *Id.* at 1233-34. The Tenth Circuit applied *Grable*, explaining that "even though a plaintiff asserts only claims under state law, federal-question jurisdiction may be appropriate if the state-law claims implicate significant federal issues." *Id.* at 1232.

The court in *Nicodemus* dutifully considered whether proof of plaintiffs' state-law claims would require resolution of a substantial, disputed federal issue. *See id*. at 1234-35. After determining that a federal issue – whether Union Pacific's "use of the right-of-way [had] exceeded the purpose for which it was granted" – would indeed arise in plaintiffs' case-in-chief, the court analyzed whether that federal issue was "substantial" under *Grable*. *Id*. at 1234-36.

The court found that the issue involved "considerable federal interests" and exercised federal question jurisdiction. *Id*. at 1236.[1]

B. Plaintiff's Amended Complaint Raises Substantial and Disputed Issues of Federal Law.

In its motion to remand, the State mischaracterizes defendants' basis for removing this case. According to the State, defendants assert that this case is removable because it is a Medicaid recovery action. (*See, e.g.*, Pl. Mot. at 8, 13-16.) In fact, this case is removable because the State's claims depend on proof that the State is authorized under the Federal Medicaid statute to refuse to reimburse for the prescription costs that it now claims "should not have been reimbursed" or are "not reimbursable." (Am. Compl. ¶¶ 10, 26, 34.) Resolving the issue of what the State is statutorily authorized to do requires the interpretation and application of the Federal Medicaid statute, which (1) determines which prescription medicines a state *must*

[1] Other post-*Grable* courts have also concluded that federal jurisdiction existed over plaintiffs' state-law claims in circumstances similar to those found here. *See, e.g.*, *County of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1237, 1244 n.5 (9th Cir. 2009) (agreeing with district court's exercise of federal question jurisdiction when, to resolve a dispute, the court had to construe a term in a federal statute); *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 195-96 (2d Cir. 2005) (exercising federal question jurisdiction where state-law claims required court to decide whether defendants violated Communications Act of 1934); *Municipality of San Juan v. Corporacion para el Fomento Economico de la Ciudad Capital*, 415 F.3d 145, 148 (1st Cir. 2005) (holding that where propriety of defendant's conduct "turns entirely on its adherence to the intricate and detailed set of federal regulatory requirements, and the funds at issue are federal grant monies," federal question jurisdiction is proper under *Grable*); *In re Pharm. Indus. AWP Litig.*, 457 F. Supp. 2d 77, 81 (D. Mass. 2006) (holding that interpretation of provision of Federal Medicare statute raised substantial federal question and that exercise of federal jurisdiction was "unlikely to upset any balance because of the substantial number of similar cases that are already pending in federal courts"); *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005) (invoking federal question jurisdiction because plaintiff's state-law claims against drug manufacturers for allegedly overcharging for drugs raised substantial federal questions under Federal Medicaid and price-control statutes); *see also In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 07-CV-1933, 2008 WL 398378, at *5 (E.D.N.Y. Feb. 12, 2008) (unpublished) (hereinafter "*Montana v. Eli Lilly*") (copies of all unpublished cases cited in this memorandum are attached hereto as Exhibit A); *In re Zyprexa Prods. Liab. Litig*, Nos. 04-MD-1596, 07-CV-645, 2007 WL 1601482, at *1 (E.D.N.Y. June 5, 2007) (unpublished) (hereinafter *Mississippi v. Eli Lilly*); *In re Zyprexa Prods. Liab. Litig*, 476 F. Supp. 2d 230, 233 (E.D.N.Y. 2007) (hereinafter *West Virginia v. Eli Lilly*); *In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170, 172-73 (E.D.N.Y. 2005) (hereinafter *Louisiana v. Eli Lilly*) (all discussed below).

reimburse for under its Medicaid program; (2) sets forth the limited circumstances under which a state may decline to pay for covered medicines; and (3) defines the term "medically accepted." *See* 42 U.S.C. § 1396r-8(d)(1)(B), (d)(4), (k)(6).

1. The State's claims raise disputed federal issues regarding the interpretation and application of the term "medically accepted" under the Federal Medicaid statute.

The State has placed directly at issue its reimbursement rights and obligations under the Federal Medicaid statute with respect to Risperdal and Seroquel prescriptions written for Utah Medicaid participants for FDA-approved and otherwise "medically accepted" uses. Indeed, in its motion to remand, the State conceded this, acknowledging that it "will need to prove . . . whether the State paid money for drugs to Medicaid recipients for uses that were not FDA-approved o[r] supported by the designated compendia." (Pl. Mot. at 13.)

a. The Federal Medicaid program.

The Federal Medicaid program is "a cooperative one" between the federal government and states which conditions federal funding on a participating state's compliance with federal statutory requirements. *Arkansas Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006). Participating states receive federal funding covering part of the cost of medical assistance that the states provide to their qualifying residents. *See* 42 U.S.C. §§ 1396-1396w-5. "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Medicaid Act . . . and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990); *accord Amisub (PSL), Inc. v. Colo. Dep't of Soc. Servs.*, 879 F.2d 789, 794 (10th Cir. 1989).

In addition to the "minimum settings" that participating states are required to provide under the Federal Medicaid statute, states may provide additional benefits to eligible individuals, such as coverage for prescription drugs. *See* 42 U.S.C. § 1396b(i)(10)(A). If a state elects to provide a prescription drug benefit, as Utah has done, it must comply with certain federal requirements set forth in 42 U.S.C. § 1396r-8. First, in order for a medicine prescribed in the state to qualify for federal funding, the medicine's manufacturer must have entered into a Medicaid Rebate Agreement with the United States Secretary of Health and Human Services, under which the manufacturer agrees to provide the medicine to state Medicaid programs at favorable prices. *Id.* § 1396r-8(a)(1), (c). At all relevant times, Janssen and AstraZeneca, separately, were parties to and complied with such agreements, covering Risperdal and Seroquel, respectively.

Second, participating states must reimburse for a manufacturer's "covered outpatient drug," with very limited exceptions and few permissible restrictions. *See id.* § 1396r-8(d); *see also Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). A "covered outpatient drug" is a drug that "is approved for safety and effectiveness as a prescription drug" by the FDA and that is prescribed for outpatient use, subject to some exceptions, for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(2)(A)(i), (k)(3). The "term 'medically accepted indication' means any use for a covered outpatient drug which is [FDA] approved, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in" the Federal Medicaid statute. *Id.* § 1396r-8(g)(1)(B)(i), (k)(6).

Accordingly, with only limited exceptions – none of which the State invokes here – as long as a use is supported by one of the specified compendia, the Federal Medicaid statute

requires participating states to reimburse prescriptions for not only FDA-approved uses, but also off-label uses supported by the compendia. *See, e.g.*, *Edmonds v. Levine*, 417 F. Supp. 2d 1323, 1341 (S.D. Fla. 2006) (concluding that Florida's attempt to limit Medicaid coverage of Neurontin violated federal law because it restricted coverage for unapproved, off-label uses listed in compendia); *see also Weaver v. Reagen*, 886 F.2d 194, 200 (8th Cir. 1989) (finding Federal Medicaid statute prohibited state program from limiting coverage to only FDA-approved indications).

b. The State's Amended Complaint raises disputed federal questions regarding the interpretation and application of the federal term "medically accepted."

There is federal question jurisdiction over this case because proof of certain of the State's claims, including the claims in Counts I and IV, requires adjudication of federal questions. *See Nicodemus*, 440 F.3d at 1234-35. In Count I, the State maintains that it need not reimburse for any off-label uses of Risperdal and Seroquel because off-label uses are not for "medically accepted indications." (*E.g.*, Am. Compl. ¶¶ 125-28, 130.) In Count IV, the State seeks to collect damages for *all* Risperdal and Seroquel prescriptions, regardless of whether they were for FDA-approved or otherwise "medically accepted" uses. (*Id.* ¶¶ 146-52.) To prevail on either Count I or Count IV, the State must prove that the Federal Medicaid statute allowed the State to refuse to reimburse for the underlying prescriptions. In either instance, the State's ability to establish its right to refuse reimbursement turns on the interpretation and application of the term "medically accepted" as used in the Federal Medicaid statute, 42 U.S.C. § 1396r-8(k)(6).

The State concedes that the interpretation of the term "medically accepted" is solely a question of federal law: the "term ['medically accepted'] cannot be found in any of the Utah

statutes alleged to have been violated." (Pl. Mot. at 9.) Moreover, the State acknowledges, as it should, that it *must* prove whether its reimbursements were for prescriptions for "medically accepted" indications: "The State will need to prove . . . whether the State has paid money for drugs to Medicaid recipients for uses that were not FDA-approved o[r] supported by the designated compendia." (*See id.* at 13.) Thus, the State is wrong to suggest that the federal question need not be decided or is "irrelevant." (*Id.* at 8.)

The State next erroneously asserts that "there is no *actual dispute* regarding the meaning of 'medically accepted.'" (*Id.* at 9.) That is incorrect. The interpretation and application of that federally defined term is at the core of this dispute. For example, the State takes the position in its Amended Complaint that off-label uses are not "medically accepted" uses. In paragraph 124, it asserts that "[c]laims for 'medically accepted indications' are limited to uses approved by the FDA or uses which are supported by officially recognized compendia." (Am. Compl. ¶ 124.) Then, in paragraphs 125 and 127, it sets forth, respectively, what it claims are the FDA-approved uses for Seroquel and for Risperdal. (*Id*. ¶¶ 125, 127.) Next, in paragraphs 126 and 128, it pleads that "Neither the compendia . . . nor the FDA support the use of [Seroquel or Risperdal] for "any . . . use not listed" in paragraphs 125 and 127. (*Id.* ¶¶ 126, 128.) Defendants dispute this proposed limitation of the term "medically accepted" to on-label uses. The Federal Medicaid statute defines "medically accepted indication" to include uses that are FDA approved *and* off-label uses supported by one of the designated compendia. *See* 42 U.S.C. § 1396r-8(k)(6). The mere fact that the issue is both disputed and material to the State's claims – regardless of who is correct – will necessarily require the court to decide a disputed issue of federal law.

Defendants also dispute the broad claim, advanced by the State in Count IV, that it can refuse to pay for any and all prescriptions of Risperdal and Seroquel because defendants each supposedly made "misrepresentations" about its medicine. (*See* Am. Compl. ¶¶ 148, 151-52.) The Federal Medicaid statute explicitly identifies the limited circumstances under which a participating state may exclude or otherwise restrict coverage of a "covered outpatient drug" such as Risperdal or Seroquel. 42 U.S.C. § 1396r-8(d). A state may deny reimbursement if the medicine has been excluded from a state-adopted formulary pursuant to 42 U.S.C. § 1396r-8(d)(4)(C) (allowing exclusion of a medicine from a formulary only when the state makes certain findings about comparative safety and efficacy and provides a written explanation, available to the public, of the basis for the exclusion). It may also "exclude or otherwise restrict coverage of a covered outpatient drug" if (1) the restrictions are part of an agreement between the drug's manufacturer and the state which has been authorized by the Secretary of Health and Human Services, or (2) the drug is on the federal statute's "list of drugs subject to restriction." *Id.* § 1396r-8(d)(1)(B), (2); *see also In re Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2010 WL 2649513, at *19-21 (E.D. La. June 29, 2010) (unpublished). The State here does not invoke any of these statutory exceptions to mandatory coverage, and to the extent they are implicated, the scope of these federal regulations is unmistakably a federal question.

Finally, defendants dispute the narrower claim that the FDA-approved and "medically accepted" indications for Risperdal and Seroquel were limited to "symptoms . . . caused by adult schizophrenia, bipolar I disorder and autism." (Am. Compl. ¶ 34(c).) In fact, until 2002, the FDA-approved use for both medicines was broadly stated as the "management of the manifestations of psychotic disorders." After the FDA-approved indication was narrowed to the

treatment of schizophrenia and bipolar disorder, the previous broad indication continued to be supported by the compendia, and therefore, such uses were "medically accepted" within the meaning of the Federal Medicaid statute. *See, e.g.*, Am. Soc'y of Health-Sys. Pharmacists, AHFS 2008 Drug Info. 2479 (2008) ("Quetiapine [Seroquel] is used for the symptomatic management of psychotic disorders . . . ."); *id.* at 2483 ("Risperidone [Risperdal] is used for the symptomatic management of psychotic disorders."); U.S. Pharmacopoeia Dispensing Info., 1 Drug Info. for the Health Care Prof'l 2536 (27th ed. 2007) ("Risperidone is used to treat the manifestations of psychotic disorders.").

In sum, whether the State is correct that it could "exclude . . . coverage" for Risperdal and Seroquel – including for prescriptions for "medically accepted" uses – depends entirely on the interpretation and application of the prescription drug reimbursement provisions of the Federal Medicaid statute. *See* 42 U.S.C. § 1396r-8(d); *see also Pharm. Research*, 538 U.S. at 652. Whether and under what circumstances the Federal Medicaid statute authorizes the State to refuse to pay for prescriptions for "medically accepted" uses is a quintessential federal question.

2. The disputed federal questions embedded in the State's claims are substantial.

The federal questions that the Amended Complaint raises about the Federal Medicaid statute are "important issue[s] of federal law that sensibly belong[] in a federal court." *Grable*, 545 U.S. at 315. They are substantial, and federal jurisdiction is warranted, because of the important federal interest in the uniform interpretation of the intricate federal reimbursement scheme in the Federal Medicaid statute. *See id.* at 312; *Nicodemus*, 440 F.3d at 1236.

In four other decisions directly on point, the court exercised federal jurisdiction over states' suits that mirror the State's claims here, holding that the substantial federal questions on

which the states' claims depended warranted federal jurisdiction. *Montana v. Eli Lilly*, 2008 WL 398378, at *1; *Mississippi v. Eli Lilly*, 2007 WL 1601482, at *1; *West Virginia v. Eli Lilly*, 476 F. Supp. 2d at 232; *Louisiana v. Eli Lilly*, 375 F. Supp. 2d at 171. As explained in *West Virginia v. Eli Lilly*, "the question of the state's obligation to reimburse its insureds for [the atypical antipsychotic] Zyprexa, using funds largely provided by the federal government, is essential to the state's theory of damages and presents a substantial and disputed federal issue under *Grable*." 476 F. Supp. 2d at 233. In this sense, the suits by Montana, Mississippi, West Virginia, and Louisiana are indistinguishable from this case.[2]

Similarly, in refusing to remand a case brought by the State of Arizona against pharmaceutical manufacturers in the Average Wholesale Price ("AWP") MDL, the court recognized that federal courts have jurisdiction to hear disputes that hinge on an interpretation of terms in the Federal Medicaid statute: "that the meaning of AWP in the federal Medicare statute is a substantial federal issue that properly belongs in federal court." *In re Pharm. Indus. AWP Litig.*, 457 F. Supp. 2d at 80-81 (concluding that the meaning of a Medicare term had "national significance" because it would apply in current and future disputes and would determine whether overpayment had been made); *cf. Abbeville Gen. Hosp. v. Ramsey*, 3 F.3d 797, 803-04 (5th Cir.

[2] The State mischaracterizes these *Zyprexa* decisions. The *Zyprexa* court held that there was federal jurisdiction over the *Montana*, *Mississippi*, *West Virginia*, and *Louisiana* actions because the four cases turned on the construction and application of federal statutory law – before the states could recover, they had to establish the applicability of the narrow exceptions to the mandatory reimbursement provisions of the Federal Medicaid statute and/or they had to establish that the marketing of Zyprexa violated federal prescription drug marketing law. The court did not hold that there is federal jurisdiction over all Medicaid recovery actions or all cases involving federal funding. But, the fact that funds at issue were "largely provided by the federal government" – as they are in this case – contributed to the substantiality of the federal questions raised in the four *Lilly* cases. *See, e.g.*, *Montana v. Eli Lilly*, 2008 WL 398378, at *3; *see also Nicodemus*, 440 F.3d at 1236 (determining that federal question was substantial in part due to the federal government's reversionary interest in the property at issue); *Municipality of San Juan*, 415 F.3d at 148 n.6 (upholding jurisdiction in part due to the fact that "the funds at issue are federal grant monies").

1993) (deferring to federal agency interpretation of Medicaid law in part due to "the need for . . . uniform construction of federal law" and in part due to "general principles of federalism, which do not permit states to be final arbiters of their compliance with federal law" (citation omitted)).

The State cites *Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986), for the proposition that Medicaid recovery claims are not "substantial" for jurisdictional purposes because there is no private right of action under the Federal Medicaid statute. (Pl. Mot. at 17-18.) But the State relies on a reading of *Merrell Dow* that did not survive *Grable*. (*E.g.*, *id.* at 17 (referring to the statement in *Merrell Dow* that the absence of a federal private right of action is "tantamount to a . . . conclusion" that there should be no federal question jurisdiction).) After *Grable*, the existence of a federal private right of action is merely "relevant to, but not dispositive of, the 'sensitive judgments about congressional intent' that [28 U.S.C.] § 1331 requires." 545 U.S. at 318 (quoting and clarifying *Merrell Dow*, 478 U.S at 810). For the same reason, the State's reliance on *Pennsylvania v. TAP Pharmaceutical Products, Inc.*, 415 F. Supp. 2d 516 (E.D. Pa. 2005), is misplaced. (*See* Pl. Mot. at 8.)

Plaintiff also cites to *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677 (2006), and, more specifically, the court's reliance in *Utah v. Eli Lilly & Co.*, 509 F. Supp. 2d 1016, 1023 (D. Utah 2007), on *Empire*, as supportive of its non-substantiality arguments. (Pl. Mot. at 19.) But the federal question presented in *Empire*, unlike the federal question presented here, was tangential and relatively unimportant. In *Empire*, the United States, as *amicus curiae*, argued that there was jurisdiction under *Grable* because "federal law is a necessary element of [Empire's] claim." *Empire*, 547 U.S. at 690. The federal question identified by the United States, however, was peripheral: "the extent, if any, to which the reimbursement [of a federal

health insurance program] should take account of attorney's fees expended . . . to obtain the [insured employee's] tort recovery." *Id*. at 701. The *Empire* Court said simply that the tag-along issue of the calculation of damages was not "substantial" enough – i.e., that the federal interest in having a federal court determine the relatively insignificant "damages calculation" issue was not nearly as strong as the federal interest in *Grable*.

In addition, plaintiff cites to *Massachusetts v. Philip Morris Inc.*, 942 F. Supp. 690 (D. Mass. 1996), to support its substantiality argument (Pl. Mot. at 18), but the quoted holding, 942 F. Supp. at 696, addresses only whether the fact that Medicaid recovery actions are authorized by federal law means that they necessarily present substantial federal questions, not whether a particular Medicaid recovery action presents federal questions warranting the exercise of federal jurisdiction. The court held that federal authorization of Medicaid recovery actions did not, in and of itself, provide a basis for federal jurisdiction. But, in two separate notes, the court explicitly acknowledged the possibility that some Medicaid recovery actions would assert substantial federal claims requiring the construction and application of federal law. *Id.* at 694 n.3, 695 n.5. Likewise, in *New York v. Lutheran Center for the Aging, Inc.*, 957 F. Supp. 393, 402 (E.D.N.Y. 1997), to which the State also cites, the court held that federal authorization of state-law Medicaid recovery actions was not itself a basis for removal, but distinguished the case from one that "turned on the interpretation of [a] term . . . defined in a federal statute, which this Court views as a clear ground to invoke federal question jurisdiction." *Id.* at 402. Plaintiff also cites to *Hawaii v. Abbott Laboratories*, 469 F. Supp. 2d 842, 852-53, 856 (D. Haw. 2006), a case in which the federal question was determined no longer to be important because the disputed term was no longer in the federal statute; and *Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d

576, 585 (E.D. Pa. 2007), which addressed "substantiality" arguments regarding congressional intent not made by defendants here.

All of these cases are distinguishable. As *Grable* makes clear, "substantiality" turns on the nature of the issue and the context in which it is raised, and the determination must be made on a case-by-case basis. 545 U.S. at 318 (stressing the need for a "contextual enquiry"). Here, plaintiff's own allegations make clear that its right to recovery depends on the resolution of the parties' dispute about the interpretation and proper application of a federal statute. Moreover, resolution of this federal question has important implications for the administration – and the uniformity, among the states – of the federal/state Medicaid programs. The federal question is indeed "substantial."

3. Plaintiff's reliance on a "tally" of cases is not the "contextual enquiry" mandated by *Grable.*

As support for an exceptionally narrow reading of *Grable* and a finding of no federal question jurisdiction, the State relies upon a simple comparison of the number of opinions granting versus denying remand, including in its "tally" *Utah v. Eli Lilly*, 509 F. Supp. 2d 1016; *Pennsylvania v. Eli Lilly*, 511 F. Supp. 2d 576; *South Carolina v. Janssen Pharmaceutica, Inc.*, No. 6:07-1452, 2007 WL 2022173 (D.S.C. July 10, 2007) (unpublished); and the cases following *Pennsylvania v. Eli Lilly* and *South Carolina v. Janssen Pharmaceutica*. (Pl. Mot. at 11-18.)[3]

[3] *Pennsylvania v. Eli Lilly* is distinguishable and should not be followed here because there, the court: (1) misconstrued *Grable*'s requirement that the federal question be "an essential element" of a state-law claim in relying on the fact that the federal question posed did not "define the entire scope of permissible conduct under [all the state laws cited in the complaint]," 511 F. Supp. 2d at 582; (2) read the "Medicaid fraud" claim as seeking recovery on federal grounds and entirely non-federal grounds, *id.* at 581-82, whereas plaintiff here has not advanced alternative non-federal grounds for recovery in its "Medicaid fraud" claim; and (3) did not address one of the issues here – whether the Federal Medicaid statue authorizes plaintiff to refuse to reimburse for *all* Risperdal and Seroquel prescriptions. Similarly, *South Carolina v. Janssen Pharmaceutica* should not be followed here because of its

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Tallies, however, are no substitute for the "contextual enquiry" into the particular allegations of the case mandated by *Grable*. *See* 545 U.S. at 318. And the required "contextual enquiry" leads to the conclusion that removal is proper here.

Furthermore, this case has not been "decided in *Utah v. Eli Lilly & Co.*" (Pl. Mot. at 11), which adopted in part the flawed reasoning of *Pennsylvania v. Eli Lilly* and *South Carolina v. Janssen Pharmaceutica*. *See Utah v. Eli Lilly*, 509 F. Supp. 2d at 1021. In *Utah v. Eli Lilly*, the court found that the State's claims against Lilly did not necessarily turn on the resolution of a question of federal law. The court explained that the State had advanced three alternative bases for its Utah False Claims Act cause of action: (1) Lilly's facilitation of Medicaid claims for prescriptions that were not "medically necessary" in violation of Utah Admin. Code R. 414-1-2(18); (2) Lilly's facilitation of claims for prescriptions that were not for "medically accepted indications" under 42 U.S.C. § 1396r-8(k)(3); and (3) Lilly's facilitation of claims for

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reliance on *Pennsylvania v. Eli Lilly* and the fact that it did not address whether the Federal Medicaid statue authorizes plaintiff to refuse to reimburse for *all* Risperdal and Seroquel prescriptions. *South Carolina v. Janssen Pharmaceutica*, 2007 WL 2022173, at *2 The cases following *Pennsylvania v. Eli Lilly* and *South Carolina v. Janssen Pharmaceutica* should not be followed for these same reasons. *See South Carolina v. Eli Lilly & Co.*, No. 7:07-1875, 2007 WL 2261693 (D.S.C. Aug. 3, 2007) (unpublished) (relying on *Pennsylvania v. Eli Lilly* without distinct analysis); *Arkansas v. Janssen Pharmaceutica, Inc.*, No. 4:07-CV-001210 (E.D. Ark. Mar. 25, 2008, Doc. No. 33) (unpublished) (order "adopt[ing] in full" the remand order in *South Carolina v. Janssen Pharmaceutica*); *Arkansas v. AstraZeneca Pharms. LP*, No: 4:08CV00601, 2008 WL 3992746 (E.D. Ark. Aug. 25, 2008) (unpublished) (adopting *Arkansas v. Janssen Pharmaceutica* in full); *New Mexico v. Ortho-McNeil-Janssen Pharms., Inc.*, No. 08-CV-00779 (D.N.M. Jan. 26, 2009, Doc. No. 23) (unpublished) (following *Pennsylvania v. Eli Lilly*); *Hood v. Ortho-McNeil-Janssen Pharms., Inc.*, Civ. No. 1:08CV166, 2009 WL 561575 (N.D. Miss. Mar. 4, 2009) (unpublished) (relying on *South Carolina v. Eli Lilly*); *South Carolina v. AstraZeneca Pharms. LP*, No. 7:09-387, 2009 WL 1227848 (D.S.C. May 5, 2009) (unpublished) (relying on *South Carolina v. Eli Lilly*); *New Mexico v. AstraZeneca Pharms. LP*, No. 09-CV-0390 (D.N.M. July 16, 2009, Doc. No. 26) (unpublished) (failing to apply or address *Grable*). Nor should this Court rely on cases that have provided no analysis or an incomplete analysis of the federal questions presented to them. *See Montana v. Janssen, LP*, No. 09-58 (D. Mont. Nov. 30, 2009, Doc. No. 15) (unpublished); *Alaska v. Eli Lilly & Co.*, No. 3:06-CV-88, 2006 WL 2168831 (D. Alaska July 28, 2006) (unpublished); *Louisiana v. Janssen Pharmaceutica Inc.*, No. 04-cv-2575 (W.D. La. June 21, 2005, Doc. No. 51) (unpublished).

prescriptions that were for "experimental, investigational, and unproved medical practices." *Id.* at 1022 (citation omitted). The court recognized that the "medically accepted indications" basis for the claim involved a federal question, but because the Utah False Claims Act cause of action could be decided on alternative bases which did not implicate federal law, the court remanded.

Plaintiff's claims here are significantly different. In the Utah False Claims Act claim against Janssen and AstraZeneca in Count I, the State seeks to recover only because Risperdal and Seroquel were allegedly promoted for indications that are not "medically accepted." The State has not, as in *Utah v. Eli Lilly*, asserted alternative bases for recovery that avoid the need for the interpretation and application of a term given its meaning by the Federal Medicaid statute. (*See* Am. Compl. ¶¶ 121-32.)

More important, neither *Utah v. Eli Lilly* nor any of the other "atypical antipsychotic" cases relied upon by plaintiff addressed a question presented here: whether the Federal Medicaid statute allows the State to recover funds expended for *all* Risperdal and Seroquel prescriptions, even for uses that were "medically accepted." (*See id.* ¶¶ 146-52; Notice of Removal ¶¶ 22-23.) Having elected to take federal dollars and volunteered to participate in the Federal Medicaid prescription drug program pursuant to 42 U.S.C. § 1396b(i)(10)(A), the State's pharmaceutical reimbursement obligations are defined by federal law. *See* 42 U.S.C. § 1396r-8. It therefore follows that the State's theory that it need not have reimbursed for *any* Risperdal and Seroquel prescriptions (and that defendants should, in turn, reimburse it for past payments the State has already made) requires that the State show that (1) it had the right under the Federal Medicaid statute to refuse to reimburse for all Risperdal and Seroquel prescriptions for Utah Medicaid participants, including prescriptions for FDA-approved and "medically accepted" uses; and (2) it

is entitled to a damages remedy from defendants under the Federal Medicaid statute if it had such a right of refusal but did not exercise it. No matter how the State titles the various counts in the Amended Complaint, clearly a core issue in this litigation is the scope of the rights and obligations of participating states under the Federal Medicaid statute. *See Edmonds*, 417 F. Supp. 2d at 1341 ("By applying a more stringent test for drug coverage than the one set out by Congress, [Florida Medicaid] is effectively denying coverage for those drugs it is legally required to cover.").

III. THE EXERCISE OF FEDERAL JURISDICTION OVER THIS CASE WILL NOT UPSET THE BALANCE OF FEDERAL AND STATE JUDICIAL RESPONSIBILITIES.

If a case presents a substantial, disputed federal issue and assertion of federal jurisdiction over the case would not "disturb[] any congressionally approved balance of federal and state judicial responsibilities" then exercise of federal jurisdiction is appropriate. *Grable*, 545 U.S. at 314. Analysis of the proper balance under the federal system examines the strength of the federal interest, *id*. at 315, and any "disruptive portent in exercising federal jurisdiction," *id*. at 314.

The exercise of federal jurisdiction here will further a strong and direct federal interest in the uniform interpretation of the intricate federal regulatory schemes involving the Federal Medicaid statute. *West Virginia v. Eli Lilly*, 476 F. Supp. 2d at 234; *In re Pharm. Indus. AWP Litig.*, 457 F. Supp. 2d at 81-82; *Louisiana v. Eli Lilly*, 375 F. Supp. 2d at 172-73. Furthermore, assertion of federal jurisdiction over this action would scarcely cause a ripple in the "normal currents of litigation" in the federal court system. *See West Virginia v. Eli Lilly*, 476 F. Supp. 2d at 234 (exercise of federal jurisdiction over the "Attorney General's action implicating the

federal Medicaid laws will not attract 'a horde of original filings and removal cases raising other state claims with embedded federal issues'" (quoting *Grable*, 545 U.S. at 318)). This suit by one of only fifty states is vastly different from *Merrell Dow*, which involved personal injury claims by one of a countless number of potential private plaintiffs who could have brought similar claims. Moreover, other state-plaintiff cases already are proceeding in federal court. (*See* Notice of Removal ¶ 27); *see also In re Pharm. Indus. AWP Litig.*, 457 F. Supp. 2d at 81 (exercising federal jurisdiction over state-law fraud claims by state plaintiff regarding Medicare drug pricing and explaining that doing so was "unlikely to upset any balance because of the substantial number of similar cases that are already pending in federal courts").

Contrary to the State's suggestion (*e.g.*, Pl. Mot. at 18), defendants do not contend that all state actions to recover Medicaid funds raise substantial federal issues or that there is federal jurisdiction in a case like this simply because Medicaid reimbursements are partly federally funded. Rather, defendants' position is that *this* Medicaid recovery action does turn on disputed and substantial issues of federal law. Here, the State asserts claims that directly implicate the scope and requirements of prescription drug coverage under the Federal Medicaid statute. Consistent with *Grable*, such claims are appropriate for consideration in a federal forum. *See, e.g.*, *Montana v. Eli Lilly*, 2008 WL 398378, at *1; *Mississippi v. Eli Lilly*, 2007 WL 1601482, at *1; *West Virginia v. Eli Lilly*, 476 F. Supp. 2d 232; *Edmonds*, 417 F. Supp. 2d at 1341; *Louisiana v. Eli Lilly*, 375 F. Supp. 2d 171.

Furthermore, the failure of the Federal Medicaid statute to provide explicitly that a recovery action might be brought in federal court – the linchpin of the State's "congressional intent" argument – is just as easily reconcilable with defendants' position as with the State's.

Since long before any statutes relating to Medicaid were enacted, Congress's intent, as expressed in 28 U.S.C. § 1331, has been that there be a federal forum for cases involving substantial federal questions. *See, e.g.*, *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180, 199 (1921). The fact that Congress has not provided for federal jurisdiction over all state Medicaid recovery actions does not dictate the conclusion that Congress did not intend there to be jurisdiction under § 1331 over Medicaid-related suits, such as this one, that involve substantial and disputed federal questions.

Finally, that the State is the plaintiff in this action does not alter the balance of state and federal judicial responsibilities. Plaintiff cites to *dictum* in a footnote in *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 21 n.22 (1983), where the Court said, "it is perhaps appropriate to note that considerations of comity make us reluctant to snatch cases which a State has brought from the courts of that State, unless some clear rule demands it." (*See* Pl. Mot. at 20.) When read in context, however, that *dictum* does not counsel against federal jurisdiction over the State's claims here. In *Franchise Tax Board*, the Court considered federal jurisdiction over declaratory judgment "suits by the States to declare the validity of their regulations despite possibly conflicting federal law," as to which the jurisdictional rules were "somewhat unclear." 463 U.S. at 19, 21. This suit, obviously, is quite different. It involves a federally funded and extensively regulated program in which the State voluntarily participates on the condition of satisfying federally imposed requirements, in exchange for Federal Medicaid dollars. It also involves claims for money damages rather than a declaration of the validity of a state law. Indeed, this case involves the almost exact opposite scenario – an attempt by a state to redefine rights and obligations that have been imposed on it under a federal law. This is

precisely why federal jurisdiction is appropriate. And, unlike in *Franchise Tax Board*, the applicable federal jurisdictional rule is well-settled.

CONCLUSION

This Court has federal jurisdiction over the State's claims under 28 U.S.C. § 1331 and *Grable*. For all of the reasons set forth above and in defendants' Notice of Removal, defendants respectfully request that this Court deny the State's motion to remand.

Respectfully submitted,

Dated: July 19, 2010.

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2010, a true and correct copy of the foregoing Defendants' Joint Memorandum in Opposition to Plaintiff's Motion to Remand for Lack of Subject Matter Jurisdiction was filed electronically with the Clerk of Court using the CM/ECF system, which sent a notice of electronic filing to the following counsel of record:

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